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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,571	07/25/2003	Susan J. Drapeau	4002-3473	9546

7590 05/03/2007  
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EXAMINER
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ROOKE, AGNES BEATA

ART UNIT	PAPER NUMBER
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1656

MAIL DATE	DELIVERY MODE
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05/03/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/626,571

Applicant(s)

DRAPEAU ET AL.

Examiner

Agnes B. Rooke

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1, 3-7, 11, 12, 20, 26-28, 49-53 and 56-66 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5, 6, 11, 12, 20, 26-28, 49-53, 56-59, 61 is/are rejected.
- 7) ☒ Claim(s) 4, 7, 52, 60 and 62 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1656

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/09/2007 has been entered.

The amendments to the claims filed on 02/09/2007 have been acknowledged.

### ***Status of the Claims***

Claims 1, 3-7, 11, 12, 20, 26-28, 49-53, and 56-66 are pending and currently under examination. Claims 2, 8-10, 13-19, 21-25, 29-48, 54, and 55 are cancelled.

**The previous rejections are withdrawn and new rejections are presented in this office action since new prior art is included to reject the claims.**

Examiner reviewed Applicants' extensive arguments regarding the previous rejections, however new prior art is presented in this office action and previous rejections over the claims are thus moot.

**NEW REJECTIONS**

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 6, 11, 12, 26, 27, 28, 49, 50, 51, 53, 56, 57, 58, 59, 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Bianchi, US 2001/0018614.

Bianchi teaches an implant for the repair of bone defects, see Abstract.

Where the osteogenic implant is crosslinked, see [0032], and where collagen is crosslinked with carbodiimide or its derivatives, see [0078]; (instant claims 1, 3, 49, 58; claim 49 is included in this rejection because the crosslink with carbodiimide will form an amide linkage).

Where the implant is porous, see [0054, 0056], and where the implant is a collagen sponge [0043]; (instant claims 1, 49, 53, 58; claim 53 is included in this rejection because the sponge maintain its capacity to maintain its shape when hydrated and regain its height following compression when hydrated).

Where the implant contains growth factors, see [0043]; (instant claims 5, 26, 27, 28, 50, 59; claims 27 and 28 are included in this rejection because the additives, such as growth factors can be bound to collagen or DBM and where the crosslinkage is not complete the additives may not be completely bound to collagen or DBM).

Where the demineralized bone matrix is present about 15-33 weight percent, see [0044]; (instant claims 6, 51).

Where the implant mold is crosslink with gamma radiation, see [0074]. (Instant claims 58, 61).

Claims 11, 12, 56, and 57 are included in this rejection because DBM comprises collagen and is therefore dispersed in collagen, where the collagen is a scaffold protein and the particle size of DBM is an inherent property produced by the method of forming the instant composition.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 20, 58, 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bianchi (U.S. 2001/0018614) in view of Boyce et al. (U.S. 2001/0043940 A1) and Boyce et al. (U.S. 2001/0043940 A1).

Sybert et al. teach the use of demineralized bone for repair of spinal disorders. At [0051] Sybert et al. state that the mechanical strength of demineralized bone (herein after referred to as DBM) can be increased by forming chemical linkages between adjacent bone particles by exposing collagen on adjacent bone particles and forming collagen-collagen bonds. At [0042] Sybert et al. state that acid is used to demineralize bone. (Claim 20)

Therefore, it would have been obvious to one skilled in the art that all crosslinking reactions would be performed under acidic conditions because Sybert et al. teach that acid is used to demineralize the bone.

Boyce et al. (U.S. 2001/0043940 A1) state that the bone particles can be combined with one or more biocompatible components, such as plasticizers [0054]; where suitable plasticizers include liquid polyhydroxy compounds as glycerol, or monoacetin etc. See [0060]. (Claims 1, 58, 64-66)

Therefore, it would have been obvious to a person having ordinary skill in the art to make a composition comprising crosslinked DBM and collagen and plasticizer because Bianchi states that the mechanical strength of DBM can be increased by forming chemical linkages between adjacent bone particles by exposing collagen on adjacent bone particles and forming collagen-collagen bonds, and further to improve the composition by including plasticizers as suggested by Boyce et al. (U.S. 2001/0043940 A1).

### ***Objection to Claims***

Claims 4, 7, 52, 60, 62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

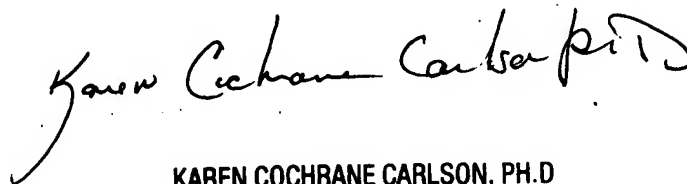
**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for unpublished applications is available through Private PAIR or Public PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR



KAREN COCHRANE CARLSON, PH.D  
PRIMARY EXAMINER